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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,881	04/18/2000	WILLIAM IAN DAVID	9267.8	6916

23973            7590            09/22/2003  
DRINKER BIDDLE & REATH  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996

[REDACTED] EXAMINER

MARSCHEL, ARDIN H

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1631

DATE MAILED: 09/22/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/463,881	DAVID ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ardin Marschel	1631	

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 30 June 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>15</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' arguments, filed 6/30/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### **TITLE**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The pending claims are all directed to a method whereas the title includes both a method and apparatus.

#### **NON-STATUTORY SUBJECT MATTER**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Consideration of the "Computer-Related Inventions" section 2106 of the MPEP in part IV has revealed that the instant claims are directed to computational or computer methods without requiring the performance of a physical transformation outside of the computation or computer. Thus, the methods manipulate concepts or convert data only. It is noted that the last 3 lines of instant claim 1 outputs at least one trial molecular crystal structure but that such an output may merely be storage of data in a compute file.

### LACK OF SCOPE OF ENABLEMENT

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the fitness calculation set forth in claim 5, does not reasonably provide enablement for any generic fitness calculation as cited without further limitation in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is reiterated and maintained from the previous office action, mailed 1/7/03. Applicants argue in REMARKS, filed 6/30/03, that mathematics is the most exact of all sciences with its corresponding low degree of unpredictability. In response,

mathematics is well known to be performed using mathematical expressions such as formulae, equations, etc. Such expressions, such as set forth in the formula in instant claim 5, is acknowledged as being exact, subject in this case to further definition of parameters (See the below set forth rejection under 35 U.S.C. 112, second paragraph.). Instant claims 1-4 and 6-11, however, are not limited to such exacting formulae and therefore lack the exacting character as argued. Due to the well known complexities of molecular modeling from diffraction data, as also summarized in Wormington et al. (P/N 6,192,103; already of record) in column 1, line 11, through column 3, line 18; specific and detailed guidance is required in order to carry out a modeling method to result in a molecular structure.

#### **VAGUENESS AND INDEFINITENESS**

Claims 5 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 sets forth a formula for fitness wherein parameters "h" and "k" are not defined. Consideration of the specification also has failed to result in definitions of what the metes and bounds of these parameters are. It is also noted that the fitness formula contains values for extracted intensity ( $I_h$  and  $I_k$ ) as well as calculated structure factor from trial structure ( $F_h$  and  $F_k$ ) whereas composite values are described in the last 4 lines of claim 5 as  $I_{h,k}$  and  $F_{h,k}$ , respectively. Although it might be guessed or assumed that  $I_h$  etc. single subscripted values in the formula are subselections from the compositely defined values, such a guess or assumption fails to be clear and concise as

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required for claim limitations under 35 U.S.C. 112, second paragraph. Clarification via clearer claim wording is requested.

In claim 8 a step is included for determining the unit cell and space group for the molecule under examination. Claim 8 depends from claim 1 wherein the unit cell and space group is predetermined. Thus, the practice of claim 8 includes both predetermined values as well as actual apparently separate determinations. The metes and bounds of what is practiced for claim 8 are unclear as to what values are utilized in the steps from claim 1 where there are two sets of values for unit cell and space group. Is one set ignored, for example? Clarification of these conflicting value usages in the practice of claim 8 is requested via clearer claim wording.

Similarly, claim 9 is directed to determining a set of internal coordinates which are already predetermined in claim 1 from which it depends. As with claim 8 clarification of what values are utilized in the practice of the claim is requested via clearer claim wording.

Claim 10 also presents an unclear conflict in that iterations are halted after completion of a predetermined number of iterations which conflicts with meeting a threshold requirement in claim 1 from which claim 10 depends. Which criteria governs the ending of iterations? Clarification via clearer claim wording is requested.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG

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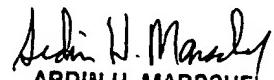
61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).  
The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 19, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER